Exactech® AcuMatch™ Integrated Hip System
L-Series Bipolar Endoprosthesis

DEC 0 5 2001

K013211

510(k) Summary of Safety and Effectiveness
Special 510(k)

Classifications / Proprietary Names:

Classification Name:	Prosthesis, Hip, Hemi-, Femoral, Metal/Polymer, Cemented or Uncemented
Product Code:	KWY
C.F.R. Section:	888.3390
Device Class:	II
Classification Panel:	Orthopedic
Trade / Proprietary Model Names:	AcuMatch L-Series Bipolar Endoprosthesis

Legally Marketed Devices for Substantial Equivalence Comparison:

Model	Manufacturer	510(k) Number
Exactech Bipolar	Exactech, Inc.	#K905370
Giliberty	Zimmer	
Bi-articular	Zimmer	
Centrax	Howmedica	
Conversion	Richards	
Self-Centering	Depuy	

Device Description:

INDICATIONS

All Exactech Hip Systems are indicated for use in skeletally mature individuals undergoing primary surgery for hip replacement due to osteoarthritis, rheumatoid arthritis, osteonecrosis, post-traumatic degenerative problems of the hip, and for treatment of proximal femoral fractures where prosthetic replacement is determined by the surgeon as the preferred treatment. Components of Exactech Hip Systems are also potentially indicated for ankylosing spondylitis, congenital hip dysplasia, revision of failed previous reconstructions where sufficient bone stock is present, and to restore mobility resulting from previous fusion.

Exactech® AcuMatch™ Integrated Hip System
L-Series Bipolar Endoprosthesis

510(k) Summary of Safety and Effectiveness
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CONTRAINDICATIONS

Exactech Hip Systems are contraindicated in patients with active infection, patients without sufficient bone stock to allow appropriate insertion and fixation of the prosthesis, in neuromuscular disorders that do not allow control of the hip joint, and in patients whose weight, age, or activity level would cause the surgeon to expect early failure of the system. The L-Series unipolar and bipolar endoprostheses are also contraindicated for use in patients with evidence of degenerative changes in the acetabulum and/or pelvic fractures.

DESIGN

The AcuMatch L-Series Bipolar is a modular two piece device consisting of a spherical cobalt chrome shell (ASTM 1537 or ASTM F75) and interchangeable polyethylene liner inserts (ASTM F638). The metal head components come in 24 sizes (38mm through 61mm). The liner options include 22, 26, 28 and 32 mm inside diameter (I.D.) offerings. The implants are supplied sterile to an assurance level (SAL) of 10^{-6}.

PERFORMANCE DATA

Functional testing and engineering analysis were conducted to verify that the implant performance would be adequate for anticipated *in vivo* load applications. This performance data includes cam-out testing, assembly testing, and a range of motion evaluation.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

DEC 0 5 2001

Ms. Lisa Simpson
Regulatory Representative
Exactech, Inc.
2320 NW 66th Court
Gainesville, Florida 32653

Re: K013211
Trade Name: AcuMatch L-Series Bipolar Endoprosthesis
Regulation Number: 21 CFR 888.3390
Regulation Name: Hip joint femoral (hemi-hip) metal/polymer cemented or uncemented prosthesis
Regulatory Class: Class II
Product Code: KWY
Dated: October 26, 2001
Received: November 6, 2001

Dear Ms. Simpson:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 21 CFR Part 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4659. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html.

Sincerely yours,

for Mark N. Melkerson

Celia M. Witten, Ph.D., M.D.
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Exactech®, Inc.

Indications for Use

510(k) Number: K013211

Device Name: AcuMatch L-Series Bipolar Endoprosthesis

INDICATIONS
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Please do not write below this line - use another page if needed.

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ___X___ OR Over the Counter Use _____

(Division Sign-Off)
Division of General, Restorative
and Neurological Devices

510(k) Number K013211